

REMARKS

Withdrawal of indicated allowability of claims in view of newly-discovered prior art is noted.

Rejected claim 150 has been cancelled.

Claim 131 has been objected to for lack of antecedent basis of a designated term. This claim has been amended in consideration of the Examiner's comment to define the invention more specifically. As amended, this claim is now submitted to be patentable to the Applicant.

Claims 70, 71, 73, 75-78, 80-82, 84-86, 88, 90-96, 98-102, 104-107, 109, 117-119, 121-130, 132-139, 142-144, 146, 148, 151-153, 155-157, 159-162 and 166 have been rejected under 35 U.S.C. §102(e) as being anticipated by Piplani et al '295. This rejection is respectfully traversed with respect to these claims as now amended.

Specifically, the independent claims 70, 75, 77, 80, 94, 108, 109, 117, 121, 137 and 140 variously recite advancing the delivery device or aligning the orifice of the graft assembly from outside the blood vessel, or "aligning an orifice of the blood flow conduit with the arteriotomy, (ii) locating a first portion of the resilient member within the blood vessel, and (iii) locating a second portion of the resilient member outside of the blood vessel," or "advancing the plurality of struts into the blood vessel through the opening," or "urging each of the plurality of struts against the interior wall of the blood vessel."

In addition, the claims which depend from these allowable independent claims are also submitted to be patentable for that reason, and additionally for the various recitations of further limitations.

These aspects of the claimed invention are not anticipated by Piplani et al. '295 which clearly relies only upon intravascular positioning of a graft 20, without any hint or suggestion of

delivering or aligning a graft with an arteriotomy or aortotomy from outside the vessel in a manner as claimed by Applicant. Nor is there any disclosure in this reference that such graft is installed extending through the arteriotomy or aortotomy in a manner as claimed by Applicant. At best, this reference discloses a bifurcated graft disposed entirely intravascularly for repairing aneurysms, and not for tapping a vessel to establish an extravascular flow of blood through the graft in a manner as claimed by Applicant. It is therefore respectfully submitted that these claims are not anticipated by, but instead are patentably distinguishable over, Piplani et al '295.

Claim 77 has been rejected under 35 U.S. C. §102(b) as being anticipated by Ersek '744. This rejection is respectfully traversed with respect to this claim as amended herein.

This claim specifically recites "aligning the orifice of the graft with the arteriotomy from outside the blood vessel; and locating the plurality of arms within the blood vessel through the arteriotomy defined therein." This aspect of the claimed invention promotes a procedure for orienting a graft with respect to an arteriotomy from outside the associated blood vessel, and is not disclosed or even suggested by the complete transplantation of the aortic bifurcation according to Ersek '744. At best, this reference discloses a tubular barrel 19 of an expander tool 18 penetrating into the graft through slit 20 during a transplantation procedure. There is thus no disclosure here of orienting a graft with respect to an arteriotomy from outside the blood vessel for establishing a conduit for blood flow outside of the vessel, in any manner resembling Applicant's claim. And, the metal members 22 of sleeve 16 and other segments of this reference cited by the Examiner offer no hint of Applicant's claimed method. It is therefore respectfully, that claim 77 is not anticipated by, but instead is patentably distinguishable over, Ersek '744.

Claims 75, 78, 121-126, 128, 131, 132, 134-136, 142 and 151 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Ersek '744 in view of Barone et al '443. This

rejection is respectfully traversed with respect to these claims as amended herein.

These claims variously recite “advancing the delivery device from outside the blood vessel toward the arteriotomy while the graft is located within the delivery device,” and “locating the plurality of arms within the blood vessel through the arteriotomy defined therein,” or “each of the plurality of struts extend laterally outwardly from an orifice of the blood flow conduit when the strut assembly is positioned in the second configuration,” or “aligning an orifice of the blood flow conduit with the arteriotomy,” or “aligning the orifice of the graft with the arteriotomy from outside the blood vessel; and locating the plurality of arms within the blood vessel through the arteriotomy defined therein,” or “inhibiting movement of the blood flow conduit in a direction away from a blood vessel in which the arteriotomy is defined due to physical interaction between the strut assembly and the blood vessel when the strut assembly is in the second configuration,” or “moving the delivery device from outside the blood vessel toward the opening defined in the blood vessel,” or “advancing the plurality of struts into the blood vessel through the opening,” or “each of the plurality of struts is maintained in the first configuration by an inner wall of the delivery device.”

These aspects of the claimed invention promote extravascular placement of a graft relative to an arteriotomy in a blood vessel to establish a blood flow conduit outside the blood vessel.

These aspects of the claimed invention are not disclosed or even suggested by the cited references considered either alone or in the combination proposed by the Examiner. These references generally disclose intravascular stent-type grafts particularly suited for repairing aortic aneurysms and, as the Examiner correctly observes, Ersek ‘744 fails to disclose use of a delivery device over the graft. And, the specific components such as the metal elements 22 and sleeve 16

of Ersek '744 offer no hint or suggestion of Applicant's claimed method.

Thus, merely combining another disclosure by Barone et al '443 of an intravascular aortic graft suitable for repairing abdominal aortic aneurysms fails to suggest any semblance of orienting a graft about an arteriotomy (or aortotomy) from outside the vessel for establishing a blood-flow conduit through the graft outside the vessel, in any manner resembling Applicant's claimed invention. Nor is there any instruction or even any incentive or motivation found in the references for combining isolated components and procedures suitable for intravascular repair, in the manner proposed by the Examiner, to yield any resemblance to Applicants' claimed invention. At best, such instruction or incentive for combining these references might only derive improperly from Applicant's own specification, but still fail to establish from these references a *prima facie* basis including Applicant's claimed elements and procedures from which a proper determination of obviousness can be formed. It is therefore respectfully, that these claims are now patentably distinguishable over the cited art.

Allowance of claims 108, 114 and 140 is noted with appreciation.

Allowability is noted of claims 72, 83, 87, 89, 97, 103, 141, 147, 149, 154, 158 and 163-165 that have been objected to for depending from rejected base claims.

These claims (except 164, 165) have been cancelled and the subject matter thereof has been substantially rewritten, including the limitations of intervening claims, and are newly presented herewith as independent claims 425-436, and the dependencies of claims 164, 165 have been corrected. Favorable consideration and allowance of these claims, and of all the remaining pending claims, are solicited.

Support for the amendments made herein to the claims is found in the specification and drawings as follows:

Claims 70, 77, and 94: “aligning ... with the arteriotomy from outside the blood vessel”; “... arms within the blood vessel through the arteriotomy ...”. Support is found, for example, in Figures 12, 13, 16, 9E and associated descriptions including at page 20, lines 1-24, and page 18, lines 16-27;

Claims 75, 80, 104, 121, and 142: “advancing (or moving) the delivery device from outside the blood vessel toward the arteriotomy ...”; “... arms within the blood vessel through the arteriotomy ...”. Support is found, for example, in Figures 13, 14, 15, 16 and 9E and associated descriptions including at page 18, lines 10-23 and page 20, lines 1-24;

Claims 81, 82, 84: “a first portion ... located adjacent to an interior sidewall ...”; “a second portion ... extend through the arteriotomy in a direction away ...”. Support is found, for example, in Figures 16, 17, 18, 19A-E, 21, 22, 23, 24 and associated descriptions including at page 20, lines 19-27;

Claim 118: “... second portion of the resilient member is attached to the first portion of the resilient member.” Support is found, for example, in Figures 9A-E and associated descriptions including page 18, line 16 to page 19, line 8;

Claim 123: “... struts extend laterally outwardly from an orifice ...”. Support is found, for example, in Figures 9B, 9E-I and associated descriptions including at page 18, lines 16-23;

Claim 130 includes only a spelling correction;

Claim 131: “... the arteriotomy is an aorta.” Support is found, for example, in Figures 3, 4, 7, 8, 12-16 and associated descriptions including page 17, line 18-26 and page 14, lines 5-19;

Claim 153: “advancing ... support from outside the blood vessel partially through the arteriotomy ...”. Support is found, for example, in Figures 13-16 and associated descriptions including page 20, lines 1-12.

Per the Examiner's request, Applicant lists all copending applications that contain claims which may be considered similar to the subject matter of the present claims, as follows:

<u>Application Serial No.:</u>	<u>Filing Date:</u>
09/903,831	July 11, 2001
10/726,803	December 2, 2003
10/824,043	April 13, 2004
10/731,068	December 8, 2003

However, Applicant declines to submit copies of the claims now pending in the applications listed above in consideration of such claims (not otherwise publicly available) becoming publicly available in the prosecution history of this application upon issuance of a patent hereon. In the event the Examiner is unable to retrieve copies of these pending claims from Patent Office files, Applicant shall submit copies of the claims for the Examiner's convenience under a procedure by which copies of those pending claims shall not appear in the prosecution history of this application.

Favorable action is solicited.

Respectfully submitted,
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